REMARKS

Claims 1-10 and 26-30 are currently pending in this application. Claim 11-25 have been canceled. Claims 1 and 26 have been amended. New claims 27-30 have been added. No new matter has been added by these amendments or additions. Applicant has carefully reviewed the Office Action and respectfully requests reconsideration of the claims in view of the remarks presented below.

Claim Rejections Under 35 U.S.C. §101

Claims 1-26 were rejected under 35 U.S.C. §101 as being directed to non-statutory subject matter. Claims 11-25 have been canceled. Claims 1-10 have been amended to recite a method involving a tangible device. Regarding claim 26 – though Applicant maintains this claim, as originally filed, recited sufficient structural limitations to be considered a patentably useful, concrete and tangible invention – it has been amended in response to §102(b) rejections and now recites further structural limitations. In view of the foregoing, Applicant requests reconsideration of the §101 rejections of claim 1-10 and 26.

Claim Rejections Under 35 U.S.C. §102

Claims 1-10 and 12-26 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,438,408 (Mulligan).

Independent claim 1 relates to a method of using an external programming system in conjunction with implanted medical devices to recommend a sequence of procedures to be performed during a follow-up consultation with a patient having an implanted medical device. The method includes performing procedures between the external programming system and an implanted device during a follow-up consultation; recording into the external programming system, information related to procedures performed between the external programming system and an implanted device during a follow-up consultation, wherein the recorded information comprises the sequence in which procedures are performed between the external programming system and an implanted device; repeating the performing and recording for one or more follow-up

consultations; analyzing the recorded information using software resident within the external programming system; and based at least in part on the analyzing, presenting information through the external programming system, the presented information indicative of a recommended sequence of procedures to be performed between the external programming system and an implanted device during a subsequent follow-up consultation with a patient having an implanted device.

Independent claim 26 relates to an external programming system for use in conjunction with implanted medical devices to recommend a sequence of procedures to be performed during a follow-up consultation with a patient having an implanted medical device. The external programming system includes a memory device; an input operative to input to the memory device, information related to procedures performed between the external programming system and one or more implanted devices during a plurality of follow-up consultations, wherein the recorded information comprises the sequence in which procedures are performed between the external programming system and the one or more implanted devices; statistical analysis software operative to analyze the procedural information; and an output operative to output one or more recommended sequence of procedures to be performed between the external programming system and an implanted device during a subsequent follow-up consultation, based at least in part on a statistical analysis of the procedural information performed using the statistical analysis software.

Regarding independent claim 1, it is noted that the purported disclosure in Mulligan, of recording information related to procedures performed by a care provider during a follow-up consultation with a patient having an implanted device (Fig. 4, column 1, lines 15-22), as cited in the Office Action, involves parameter data, *e.g.*, blood pressure, heart chamber volume (column 16, lines 50-54) and related data, *e.g.*, heart rate and patient activity level (column 17, lines 6-7), that are accumulated in the implanted device and periodically transmitted to an external programmer for display and analysis (column 17, lines 17-18). While Mulligan does disclose an external programmer, this programmer is only described as receiving data from the implanted device. This data from the implanted device relates to procedures performed by the

implantable device. See column 16, lines 55-59, wherein parameter data and related data are described as being calculated using algorithms incorporated into the microcomputer of the implanted device. Thus, with regard to claim 1, the external programmer in Mulligan does not have recorded into it, information related to procedures performed between the external programming system and an implanted device.

It is also noted that the purported disclosure in Mulligan, of the analyzing of procedures; recommending of one or more procedures for a subsequent follow-up consultation (column 9, lines 19-37 and column 17, lines 12-42) and presenting of information indicative of a recommended sequence of procedures for follow-up (column 16, lines 5-67), as cited in the Office Action, are only disclosed as being performed by a physician. Thus, Mulligan does not teach or suggest, analyzing procedural information using software resident within the external programming system; and based at least in part on the analyzing, presenting information through the external programming system, the presented information indicative of a recommended sequence of procedures to be performed between the external programming system and an implanted device during a subsequent follow-up consultation with a patient having an implanted device.

Regarding independent claim 26, it is believed novel over Mulligan for the same reasons presented above with respect to claim 1. Furthermore, it is noted that the purported disclosure in Mulligan of means for recording (column 6, lines 1-8, IMD memory); means for analyzing the procedures (Fig. 2, microcomputer 102 and input signal processing circuit 108); statistical analysis software (column 12, lines 44-67); and means for recommending one or more procedures (telemetry transceiver 124 and antenna 28), as cited in the Office Action, are all part of an implantable device. Thus, Mulligan does not disclose Applicant's claimed external programming system.

In view of the foregoing, Applicant submits that Mulligan fails to disclose the combinations of elements and features recited in independent claims 1 and 26. Accordingly, Applicant requests reconsideration of the §102 rejections of independent claims 1 and 26 and their respective dependent claims.

Claims 1-6, 9, 10, 12-22 and 24-25 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,405,087 (Snell).

Regarding independent claim 1, it is noted that the purported disclosure in Snell of the claim elements (the Abstract, figures 1 and 2 and column 8, lines 16-30), as cited in the Office Action, involves performance data, *e.g.*, paced and sensed heart rate histograms, sensor rate histograms, etc., generated by an implanted device and limit data, *e.g.*, thresholds, established and stored either in the implantable device or in the external programmer (column 2, lines 24-35 and column 7, lines 42-56). The performance data and limit data are analyzed by either the implanted device or the external device (column 8, lines 1-6). Thus, with respect to any recording of data in an external programmer, it is inherent in Snell that such data corresponds to performance data that is generated by an implanted device. Accordingly, with regard to claim 1, the external programmer in Snell is not described as having recorded into it, information related to procedures performed between the external programming system and an implanted device, wherein the information comprises the sequence in which procedures are performed between the external programming system and an implanted device. Because Snell does not disclose the recording of Applicant's claimed "recorded information," it cannot reasonably be interpreted as disclosing the analysis of such information.

It is also noted that the purported disclosure in Snell of the presenting of information indicative of a recommended sequence of procedures for follow up consultation (column 8, lines 16-30), as cited and explained in the Office Action, involves nothing more than a graded display of different levels of concern, including "notice," "warning" and "alarm," regarding the performance of the implanted device. Applicant submits that this display of different levels of concern does not correspond to Applicant's claimed presented information indicative of a recommended sequence of procedures to be performed between an implanted device and an external programmer.

In view of the foregoing, Applicant submits that Snell fails to disclose the combination of elements and features recited in independent claim 1. Accordingly, Applicant requests reconsideration of this §102 rejections of independent claim 1 and its dependent claims.

Claims 1-3, 5-6 and 8-10 and 12-26 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent Application No. 2003/0171789 (Malek).

Regarding independent claim 1, it is noted that the purported disclosure in Malek of the analysis of collected data and the recommending of procedures, as explained in the Office Action, are performed by a physician. Thus, Malek does not teach or suggest, analyzing procedural information using software resident within the external programming system; and based at least in part on the analyzing, presenting information through the external programming system, the presented information indicative of a recommended sequence of procedures to be performed between the external programming system and an implanted device during a subsequent follow-up consultation.

It is further noted that the Malek process involves a single screening phase for a single device. See figure 9. Thus Malek does not teach or suggest repeating the recording for at least one more follow-up consultation.

Regarding independent claim 26, it is believed novel over Malek for the same reasons presented above with respect to claim 1.

In view of the foregoing, Applicant submits that Malek fails to disclose the combinations of elements and features recited in independent claims 1 and 26. Accordingly, Applicant requests reconsideration of this §102 rejections of independent claims 1 and 26 and their respective dependent claims.

New Claims 27-30

New claims 27-30, which depend from claim 1, recite additional features related to the storing of presented information and to whom or what the presented information

may correspond. The prior art of record does not teach or suggest any of these features.

CONCLUSION

Applicant has made an earnest and bona fide effort to clarify the issues before the Examiner and to place this case in condition for allowance. Therefore, allowance of Applicant's claims 1-10 and 26-30 is believed to be in order.

Respectfully submitted,

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